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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,133	02/05/2002	Howard Kaufman	23328-015003	8486
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EXAMINER				
MOSS, KERI A				
ART UNIT		PAPER NUMBER		
1797				
NOTIFICATION DATE		DELIVERY MODE		
06/26/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/068,133

Applicant(s)

KAUFMAN ET AL.

Examiner

KERI A. MOSS

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33, 34, 42, 43, 48, 49, 54-56, 59-70, 72-81 and 83-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33, 34, 42, 43, 48, 49, 54-56, 59-70, 72-81, and 83-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's Request for Reconsideration filed March 12, 2009 is hereby acknowledged. Claims 33, 34, 42, 43, 48, 49, 54-56, 59-70, 72-81, and 83-87 are pending.

Response to Amendment

2. All previous rejections have been maintained.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims **33, 34, 42-43, 48, 54-56, 60-67, 70, 80-81, 83 and 87** are rejected under 35 U.S.C. 102(e) as being anticipated by Soenksen. Soenksen teaches a method of compensating for sample motion in the spectral analysis of a sample, said method comprising the steps of applying a chemical agent to a sample (column 14 lines 26-38); obtaining spectral data from said sample as a function of location using a spectrometer (paragraph bridging columns 13-14); obtaining a plurality of sequential images of said sample using a camera (column 14 lines 39-62); aligning a subset of said plurality of images to compensate for sample motion (Fig. 3c; column 20 lines 29-51), wherein said

sample motion is a relative motion between said sample and a probe with which said plurality of sequential images and said spectral data are obtained (column 6 lines 20-40). The spectral data comprises fluorescence data and inherently comprises reflectance data (columns 13-14). The chemical agent is applied topically and interacts with the sample to alter an optical signal produced by the sample (column 14 lines 26-38). Soenksen also teaches determining a characteristic of an area of the sample wherein the determining step comprises detecting an artifact wherein said artifact comprises an extraneous portion of an optical field of view (column 9 lines 8-27). The camera is a video camera and the probe comprises a video camera (column 14 lines 39-62).

5. Claims **33, 34, 42, 46, 48, 54, 59-64, 66-68, 72-81, 83 and 85-87** are rejected under 35 U.S.C. 102(e) as being anticipated by Riley et al. (USP 6,453,060 B1). Riley et al. teaches a method of compensating for sample motion in the spectral analysis of a sample, said method comprising the steps of applying a chemical agent to a sample (column 1 lines 30-57); obtaining spectral data from said sample as a function of location using a spectrometer (column 4); obtaining a plurality of sequential images of said sample using a camera (columns 4-5); aligning a subset of said plurality of images to compensate for sample motion (Fig. 1; column 4 lines 18-24), wherein said sample motion is a relative motion between said sample and a probe with which said plurality of sequential images and said spectral data are obtained (columns 15-16). The spectral data comprises reflectance data (columns 13-14). The chemical agent is applied

topically and interacts with the sample to alter an optical signal produced by the sample (column 14 lines 26-38). Riley et al. also teaches determining a characteristic of an area of the sample (column 9 lines 8-27). The optical signal is produced at least in part by an endogenous chromophore selected from the group consisting of NADH, collagen, elastin, flavin, hemoglobin and porphyrin (column 3). The spectral data are obtained at substantially the same time the images are obtained (paragraph bridging columns 3-4). Riley et al. teach the additional step correcting the location according to the aligned images (column 4). The sample may be in vivo tissue, such as cervical tissue (column 3). The aligning step comprises computing a cross-correlation of two of said sequential images, wherein two of the sequential images are successive, gradient or sum-of-derivatives images (columns 9-11). The aligning step comprises using a Hamming window, translation from cross-correlation to align the two images, validating and translation (column 9-11). The camera is a video camera and the probe comprises a video camera (column 14 lines 39-62).

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims **46, 49, 68-69 and 84** are rejected under 35 U.S.C. 103(a) as being unpatentable over Soenksen and Riley et al., supra, and further in view of Richards-Kortum et al. (USP 6,241,662).

Soenksen does not specifically teach using the device on human cervical tissue nor Soenksen expressly teach applying the chemical agent topically to the sample. Richards-Kortum et al., like Soenksen and Riley et al., teaches a device and method for determining the characteristic of an area of a sample. Richards-Kortum et al. teaches a method of detecting tissue abnormalities using spectroscopy. The advantages of this technique are that it quickly, non-invasively and quantitatively probes the biochemical and morphological changes that occur as tissue becomes neoplastic (paragraph bridging columns 1 and 2). Measured spectral information is useful for developing clinically effective screening and diagnostic techniques, especially when combined with automated data analysis techniques (paragraph bridging columns 1 and 2). Incorporating the teachings of Richards-Kortum et al. into Soenksen or Riley et al. would enable medical uses of the Soenksen or Riley et al. device, such as detection of histopathological changes in tissue. Thus it would have been obvious to couple the diagnostic methods of Richards-Kortum with Soenksen or Riley et al. in order to gain the advantages of developing clinical screening and diagnostic techniques for detecting neoplastic tissue.

Neither Soenksen nor Riley et al. disclose using a chemical agent selected from a group consisting of acetic acid, formic acid, propionic acid and butyric acid. Richards-Kortum teaches using acetic acid specifically for epithelial tissue such as cervical (column 2 lines 43-65). Acetic acid is used to distinguish normal tissue from abnormal tissue (column 4 lines 47-67), specifically precancerous tissue such as CIN II or III (column 2 lines 56-65). An advantage of acetic acid is that it enhances the optical

return signal of illuminated tissue during fluorescence microscopy (column 2 lines 43-65). Therefore it would have been obvious to one of ordinary skill in the art to combine the imaging method of Soenksen or Riley et al. with Richards-Kortum's use of acetic acid as a chemical agent for enhancing the optical signal in fluorescence detection and with Richards-Kortum's use of cervical cells in order to gain the additional advantage of detecting abnormal cervical cells.

8. Claims **72-79 and 85-86** are rejected under 35 U.S.C. 103(a) as being unpatentable over Soenksen, as applied to claims 33 and 83 above, and further in view of Maas, III et al (USP 5,850,486).

Soenksen does not expressly teach aligning the images by cross-correlation, using a hamming window, or determining a translation. Mass III teaches methods of rotational and translation correction of images using cross correlation of sub-images of two sequential images (column 6 lines 39-47), alignment using a Hamming window (column 6 lines 48-60), determining a translation from cross-correlation (column 3 line 60-column 4 line 14) and validating the translation (column 5 line 50-column 6 line 24). The sequential images are successive images and may be gradient or sum-of-derivatives images (column 4 lines 57-67). Maas III teaches that in imaging when the subject moves, it is important to register the time-series of images to remove motion artifact (column 1 lines 34-46). Removing motion artifact would improve the accuracy of the image. Therefore, it would have been obvious for one of ordinary skill in the art to

modify the method of Soenksen et al., with the techniques taught in Maas III in order to remove the motion artifact, thereby improving the accuracy of the image.

Response to Arguments

9. Applicant's arguments filed March 12, 2009 have been fully considered but they are not persuasive.

10. Applicants argue that neither Soenksen nor Riley et al. disclose "using a probe to obtain both spectral data and a plurality of images from a sample and aligning a subset of the images obtained to compensate for relative motion between the sample and the probe, as recited in claim 33," (See Request for Reconsideration filed March 12, 2009, page 9, last paragraph and page 10, third full paragraph) which "is language similar to the subject matter" in claims 83 and 87 (Id. p. 11 second full paragraph). This is a mischaracterization of the independent claims 33, 83 and 87, as explained below.

11. First, applicants have not claimed a step of using a probe. The only mention of a probe is merely an off-handed mention within a "wherein" clause. Wherein clauses raise a question as to the limiting effect of the language in a claim. MPEP § 2106 (II)(C). "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation." MPEP § 2106 (II)(C). The "wherein clause" in claims 33 and 83 is used to clarify the meaning of "sample motion." Tossing the word "probe" into the clarification of the term "sample motion" does not create a clear requirement that the steps of obtaining spectra data and obtaining a plurality of images be performed with a

probe, nor does it limit the claim to that particular structure. If applicants wish to claim such a step of using a probe, applicants must make that a definitive step within the method claim.

12. Second, the term "align" has not been defined in the specification. During examination, the claims must be interpreted as broadly as their terms reasonably allow. MPEP § 2111.01. This means that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. MPEP § 2111.01. The plain meaning of the term "align" is "to place in a line." Nothing in the instant specification is inconsistent with this interpretation. Figure 3b of Soenksen shows images in a line. Figure 1 of Riley shows images in a line. Further, the cited sections demonstrate placing images in a line. Therefore, Soenksen and Riley both show alignment of images as recited in independent claims 33, 83 and 87.

13. For the reasons above, the prior art reads on the instant claims and therefore the rejections have been maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI A. MOSS whose telephone number is (571)272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Keri A. Moss/
Examiner, Art Unit 1797
/Vickie Kim/
Supervisory Patent Examiner, Art Unit 1797